Calendar No. 617

110TH CONGRESS 2D SESSION

S. 980

To amend the Controlled Substances Act to address online pharmacies.

IN THE SENATE OF THE UNITED STATES

March 23, 2007

Mrs. Feinstein (for herself, Mr. Sessions, Mr. Biden, Mr. Coleman, Mr. Leahy, and Mr. Cornyn) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

March 12, 2008

Reported by Mr. LEAHY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Controlled Substances Act to address online pharmacies.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Online Pharmacy Con-
- 5 sumer Protection Act of 2007".

1	SEC. 2. AMENDMENTS TO THE CONTROLLED SUBSTANCES
2	ACT RELATING TO THE DELIVERY OF CON-
3	TROLLED SUBSTANCES BY MEANS OF THE
4	INTERNET.
5	(a) In General.—Section 102 of the Controlled
6	Substances Act (21 U.S.C. 802) is amended by adding at
7	the end the following:
8	"(47) The term 'Internet' means collectively the
9	myriad of computer and telecommunications facili-
10	ties, including equipment and operating software,
11	which comprise the interconnected worldwide net-
12	work of networks that employ the Transmission
13	Control Protocol/Internet Protocol, or any prede-
14	cessor or successor protocol to such protocol, to com-
15	municate information of all kinds by wire or radio.
16	"(48) The term 'deliver, distribute, or dispense
17	by means of the Internet' refers, respectively, to any
18	delivery, distribution, or dispensing of a controlled
19	substance that is eaused or facilitated by means of
20	the Internet.
21	"(49) The term 'online pharmacy'—
22	"(A) means a person, entity, or Internet
23	site, whether in the United States or abroad,
24	that delivers, distributes, or dispenses, or offers
25	to deliver, distribute, or dispense, a controlled
26	substance by means of the Internet; and

1	"(B) does not include—
2	"(i) manufacturers or distributors
3	registered under subsection (a), (b), (c), or
4	(d) of section 303 who do not dispense
5	controlled substances;
6	"(ii) nonpharmacy practitioners who
7	are registered under section 303(f);
8	"(iii) mere advertisements that do not
9	attempt to facilitate an actual transaction
10	involving a controlled substance; or
11	"(iv) a person, entity, or Internet site
12	which is not in the United States and does
13	not facilitate the delivery, distribution, or
14	dispensing of a controlled substance by
15	means of the Internet to any person in the
16	United States.
17	"(50) The term 'homepage' means the first
18	page of the website of an online pharmacy that is
19	viewable on the Internet.".
20	(b) REGISTRATION REQUIREMENTS.—Section 303 of
21	the Controlled Substances Act (21 U.S.C. 823) is amend-
22	ed by adding at the end the following new subsection:
23	"(i) DISPENSER OF CONTROLLED SUBSTANCES BY
24	MEANS OF THE INTERNET.—(1) A pharmacy that seeks
25	to deliver, distribute, or dispense by means of the Internet

- 1 a controlled substance shall obtain a registration specifi-
- 2 cally authorizing such activity, in accordance with regula-
- 3 tions promulgated by the Attorney General. In deter-
- 4 mining whether to grant an application for such registra-
- 5 tion, the Attorney General shall apply the factors set forth
- 6 in subsection (f).
- 7 "(2) Registration under this subsection shall be in
- 8 addition to, and not in lieu of, registration under sub-
- 9 section (f).
- 10 "(3) This subsection does not apply to pharmacies
- 11 that merely advertise by means of the Internet but do not
- 12 attempt to facilitate an actual transaction involving a con-
- 13 trolled substance by means of the Internet.".
- 14 (e) REPORTING REQUIREMENTS.—Section 307(d) of
- 15 the Controlled Substances Act (21 U.S.C. 827(d)) is
- 16 amended by—
- 17 (1) designating the text as paragraph (1); and
- 18 (2) inserting after paragraph (1), as so des-
- 19 ignated by this Act, the following new paragraph:
- 20 "(2) A pharmacy registered under section 303(i) shall
- 21 report to the Attorney General the controlled substances
- 22 dispensed under such registration, in such manner and ac-
- 23 companied by such information as the Attorney General
- 24 by regulation shall require.".

1	(d) Online Prescription Requirement.—Section
2	309 of the Controlled Substances Act (21 U.S.C. 829) is
3	amended by adding at the end the following new sub-
4	section:
5	"(e) Controlled Substances Dispensed by
6	MEANS OF THE INTERNET.—(1) As used in this sub-
7	section—
8	"(A) the term 'valid prescription' means a pre-
9	scription that is issued for a legitimate medical pur-
10	pose in the usual course of professional practice that
11	is based upon a qualifying medical relationship by a
12	practitioner registered by the Attorney General
13	under this part;
14	"(B) the term 'qualifying medical relation-
15	ship'—
16	"(i) means a medical relationship that ex-
17	ists when the practitioner—
18	"(I) has conducted at least one med-
19	ical evaluation with the user in the phys-
20	ical presence of the practitioner, without
21	regard to whether portions of the evalua-
22	tion are conducted by other health profes-
23	sionals; or
24	"(II) conducts a medical evaluation of
25	the patient as a covering practitioner and

1	is not prescribing a controlled substance in
2	sehedule H, HI, or IV; and
3	"(ii) shall not be construed to imply that
4	one medical evaluation described in clause (i)
5	demonstrates that a prescription has been
6	issued for a legitimate medical purpose within
7	the usual course of professional practice; and
8	"(C) the term 'covering practitioner' means,
9	with respect to a patient, a practitioner who con-
10	ducts a medical evaluation, without regard to wheth-
11	er the medical evaluation of the patient involved is
12	an in-person evaluation, at the request of a practi-
13	tioner who has conducted at least one in-person
14	medical evaluation of the patient and is temporarily
15	unavailable to conduct the evaluation of the patient.
16	"(2) In addition to the requirements of subsections
17	(a) through (e), no controlled substance may be delivered,
18	distributed, or dispensed by means of the Internet without
19	a valid prescription.
20	"(3) Nothing in this subsection shall apply to—
21	"(A) the dispensing of a controlled substance
22	pursuant to telemedicine practices sponsored by—
23	"(i) a hospital that has in effect a provider
24	agreement under title XVIII of the Social Secu-
25	rity Act; or

1	"(ii) a group practice that has not fewer
2	than 100 physicians who have in effect provider
3	agreements under such title; or
4	"(B) the dispensing or selling of a controlled
5	substance pursuant to practices as determined by
6	the Attorney General by regulation.".
7	(e) Online Prescription Requirements.—The
8	Controlled Substances Act is amended by adding after sec-
9	tion 310 (21 U.S.C. 830) the following:
10	"ONLINE PHARMACY LICENSING AND DISCLOSURE
11	REQUIREMENTS
12	"Sec. 311. (a) In General.—An online pharmacy
13	shall display in a visible and clear manner on its homepage
14	a statement that it complies with the requirements of this
15	section with respect to the delivery or sale or offer for sale
16	of controlled substances and shall at all times display on
17	the homepage of its Internet site a declaration of compli-
18	ance in accordance with this section.
19	"(b) Licensure. Each online pharmacy shall com-
20	ply with the requirements of State law concerning the li-
21	censure of pharmacies in each State from which it, and
22	in each State to which it, delivers, distributes, or dispenses
23	or offers to deliver, distribute, or dispense controlled sub-
24	stances by means of the Internet.
25	"(c) Compliance.—No online pharmacy or practi-
26	tioner shall deliver, distribute, or dispense by means of the

1	Internet a controlled substance without a valid prescrip-
2	tion (as defined in section 309(e)) and each online phar-
3	macy shall comply with all applicable requirements of Fed-
4	eral and State law.
5	"(d) Internet Site Disclosure Information.—
6	Each online pharmacy site shall post in a visible and clear
7	manner on the homepage of its Internet site or on a page
8	directly linked from its homepage the following:
9	"(1) The name of the owner, street address of
10	the online pharmacy's principal place of business,
11	telephone number, and email address.
12	"(2) A list of the States in which the online
13	pharmacy, and any pharmacy which dispenses, deliv-
14	ers, or distributes a controlled substance on behalf
15	of the online pharmacy, is licensed to dispense con-
16	trolled substances or prescription drugs and any ap-
17	plicable license number.
18	"(3) For each pharmacy identified on its license
19	in each State in which it is licensed to engage in the
20	practice of pharmacy and for each pharmacy which
21	dispenses or ships controlled substances on behalf of
22	the online pharmacy:
23	"(A) The name of the pharmacy.

"(B) The street address of the pharmacy.

1	"(C) The name, professional degree, and
2	licensure of the pharmacist-in-charge.
3	"(D) The telephone number at which the
4	pharmacist-in-charge can be contacted.
5	"(E) A certification that each pharmacy
6	which dispenses or ships controlled substances
7	on behalf of the online pharmacy is registered
8	under this part to deliver, distribute, or dis-
9	pense by means of the Internet controlled sub-
10	stances.
11	"(4) The name, address, professional degree,
12	and licensure of practitioners who provide medical
13	consultations through the website for the purpose of
14	providing prescriptions.
15	"(5) A telephone number or numbers at which
16	the practitioners described in paragraph (4) may be
17	contacted.
18	"(6) The following statement, unless revised by
19	the Attorney General by regulation: 'This online
20	pharmacy will only dispense a controlled substance
21	to a person who has a valid prescription issued for
22	a legitimate medical purpose based upon a medical
23	relationship with a prescribing practitioner, which
24	includes at least one prior in-person medical evalua-

tion. This online pharmacy complies with section

1	309(e) of the Controlled Substances Act (21 U.S.C.
2	829(e)).'.
3	"(e) Notification.—(1) Thirty days prior to offer-
4	ing a controlled substance for sale, delivery, distribution,
5	or dispensing, the online pharmacy shall notify the Attor-
6	ney General, in the form and manner as the Attorney Gen-
7	eral shall determine, and the State boards of pharmacy
8	in any States in which the online pharmacy offers to sell,
9	deliver, distribute, or dispense controlled substances.
10	"(2) The notification required under paragraph (1)
11	shall include—
12	"(A) the information required to be posted on
13	the online pharmacy's Internet site under subsection
14	(d) and shall notify the Attorney General and the
15	applicable State boards of pharmacy, under penalty
16	of perjury, that the information disclosed on its
17	Internet site under to subsection (d) is true and ac-
18	curate;
19	"(B) the online pharmacy's Internet site ad-
20	dress and a certification that the online pharmacy
21	shall notify the Attorney General of any change in
22	the address at least 30 days in advance; and
23	"(C) the Drug Enforcement Administration
24	registration numbers of any pharmacies and practi-
25	tioners referred to in subsection (d), as applicable.

1	"(3) An online pharmacy that is already operational
2	as of the effective date of this section, shall notify the At-
3	torney General and applicable State boards of pharmacy
4	in accordance with this subsection not later than 30 days
5	after the effective date of this section.
6	"(f) DECLARATION OF COMPLIANCE.—On and after
7	the date on which it makes the notification under sub-
8	section (e), each online pharmacy shall display on the
9	homepage of its Internet site, in such form as the Attorney
10	General shall by regulation require, a declaration that it
11	has made such notification to the Attorney General.
12	"(g) Reports.—Any statement, declaration, notifi-
13	eation, or disclosure required under this section shall be
14	considered a report required to be kept under this part.".
15	(f) Offenses Involving Controlled Sub-
16	STANCES IN SCHEDULES III, IV, AND V.—Section 401(b)
17	of the Controlled Substances Act (21 U.S.C. 841(b)) is
18	amended—
19	(1) in paragraph (1)—
20	(A) in subparagraph (C), by striking "1
21	gram of" before "flunitrazepam";
22	(B) in subparagraph (D), by striking "or
23	in the case of any controlled substance in
24	schedule III (other than gamma hydroxybutyric
25	acid), or 30 milligrams of flunitrazenam"; and

1 (C) by inserting at the end the following:

"(E)(i) In the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 20 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, or \$500,000 if the defendant is an individual or \$2,500,000 if the

"(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, or \$1,000,000 if the defendant is an individual or \$5,000,000 if the defendant is other than an individual, or both.

"(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the ab-

1	sence of such a prior conviction, impose a term of
2	supervised release of at least 2 years in addition to
3	such term of imprisonment and shall, if there was
4	such a prior conviction, impose a term of supervised
5	release of at least 4 years in addition to such term
6	of imprisonment";
7	(2) in paragraph (2) by—
8	(A) striking "3 years" and inserting "5
9	years'';
10	(B) striking "6 years" and inserting "10
11	years'';
12	(C) striking "after one or more prior con-
13	victions" and all that follows through "have be-
14	come final," and inserting "after a prior convic-
15	tion for a felony drug offense has become
16	final,"; and
17	(3) in paragraph (3) by—
18	(A) striking "2 years" and inserting "6
19	years'';
20	(B) striking "after one or more convic-
21	tions" and all that follows through "have be-
22	come final," and inserting "after a prior convic-
23	tion for a felony drug offense has become
24	final,"; and

1	(C) adding at the end the following "Any
2	sentence imposing a term of imprisonment
3	under this paragraph may, if there was a prior
4	conviction, impose a term of supervised release
5	of not more than 1 year, in addition to such
6	term of imprisonment."
7	(g) Offenses Involving Dispensing of Con-
8	TROLLED SUBSTANCES BY MEANS OF THE INTERNET.
9	Section 401 of the Controlled Substances Act (21 U.S.C.
10	841) is amended by adding at the end the following:
11	"(g) Offenses Involving Dispensing of Con-
12	TROLLED SUBSTANCES BY MEANS OF THE INTERNET.
13	(1) Except as authorized by this title, it shall be unlawful
14	for any person to knowingly or intentionally cause or fa-
15	eilitate the delivery, distribution, or dispensing by means
16	of the Internet of a controlled substance.
17	"(2) Violations of this subsection include—
18	"(A) delivering, distributing, or dispensing a
19	controlled substance by means of the Internet by a
20	pharmacy not registered under section 303(i);
21	"(B) writing a prescription for a controlled sub-
22	stance for the purpose of delivery, distribution, or
23	dispensation by means of the Internet in violation of
24	subsection 309(e);

1	"(C) serving as an agent, intermediary, or other
2	entity that causes the Internet to be used to bring
3	together a buyer and seller to engage in the dis-
4	pensing of a controlled substance in a manner not
5	authorized by sections 303(i) or 309(e); and
6	"(D) making a material false, fictitious, or
7	fraudulent statement or representation in the sub-
8	mission to the Attorney General under section 311.
9	"(3) This subsection does not apply to—
10	"(A) the delivery, distribution, or dispensation
11	of controlled substances by nonpractitioners to the
12	extent authorized by their registration under this
13	title;
14	"(B) the placement on the Internet of material
15	that merely advocates the use of a controlled sub-
16	stance or includes pricing information without at-
17	tempting to propose or facilitate an actual trans-
18	action involving a controlled substance; or
19	"(C) any activity that is limited to—
20	"(i) the provision of a telecommunications
21	service, or of an Internet access service or
22	Internet information location tool (as those
23	terms are defined in section 231 of the Commu-
24	nications Act of 1934 (47 U.S.C. 231)); or

1	"(ii) the transmission, storage, retrieval,
2	hosting, formatting, or translation (or any com-
3	bination thereof) of a communication, without
4	selection or alteration of the content of the
5	communication, except that deletion of a par-
6	ticular communication or material made by an-
7	other person in a manner consistent with sec-
8	tion 230(e) of the Communications Act of 1934
9	(47 U.S.C. 230(e)) shall not constitute such se-
10	lection or alteration of the content of the com-
11	munication.
12	"(4) Any person who knowingly or intentionally vio-
13	lates this subsection shall be sentenced in accordance with
14	subsection (b) of this section.".
15	(h) Publication.—Section 403(c) of the Controlled
16	Substances Act (21 U.S.C. 843(e)) is amended by—
17	(1) designating the text as paragraph (1); and
18	(2) adding at the end the following:
19	"(2)(A) It shall be unlawful for any person to use
20	the Internet, or eause the Internet to be used, to advertise
21	the sale of, or to offer to sell, distribute, or dispense, a
22	controlled substance except as authorized by this title.
23	"(B) Violations of this paragraph include eausing the
24	placement on the Internet of an advertisement that refers
25	to or directs prospective buyers to Internet sellers of con-

- 1 trolled substances who are not registered under section
- $2 \frac{303(i)}{.}$
- 3 "(C) This paragraph does not apply to material that
- 4 either—
- 5 "(i) advertises the distribution of controlled
- 6 substances by nonpractitioners to the extent author-
- 7 ized by their registration under this title; or
- 8 "(ii) merely advocates the use of a controlled
- 9 substance or includes pricing information without at-
- 10 tempting to facilitate an actual transaction involving
- 11 a controlled substance.".
- 12 (i) Injunctive Relief.—Section 512 of the Con-
- 13 trolled Substances Act (21 U.S.C. 882) is amended by
- 14 adding to the end of the section the following new sub-
- 15 section:
- 16 "(e) State Cause of Action Pertaining to On-
- 17 LINE PHARMACIES.—(1) In any case in which the State
- 18 has reason to believe that an interest of the residents of
- 19 that State has been or is being threatened or adversely
- 20 affected by the action of a person, entity, or Internet site
- 21 that violates the provisions of section 303(i), 309(e), or
- 22 311, the State may bring a civil action on behalf of such
- 23 residents in a district court of the United States with ap-
- 24 propriate jurisdiction—

1	"(A) to enjoin the conduct which violates this
2	section;
3	"(B) to enforce compliance with this section;
4	"(C) to obtain damages, restitution, or other
5	compensation, including civil penalties under section
6	402(b); and
7	"(D) to obtain such other legal or equitable re-
8	lief as the court may find appropriate.
9	"(2)(A) Prior to filing a complaint under paragraph
10	(1), the State shall serve a copy of the complaint upon
11	the Attorney General and upon the United States Attor-
12	ney for the judicial district in which the complaint is to
13	be filed. In any case where such prior service is not fea-
14	sible, the State shall serve the complaint on the Attorney
15	General and the appropriate United States Attorney on
16	the same day that the State's complaint is filed in Federal
17	district court of the United States. Such proceedings shall
18	be independent of, and not in lieu of, criminal prosecutions
19	or any other proceedings under this title or any other laws
20	of the United States.
21	"(B)(i) Not later than 120 days after the later of the
22	date on which a State's complaint is served on the Attor-
23	ney General and the appropriate United States Attorney,
24	or the date on which the complaint is filed, the United

- 1 States shall have the right to intervene as a party in any
- 2 action filed by a State under paragraph (1).
- 3 "(ii) After the 120-day period described in clause (i)
- 4 has elapsed, the United States may, for good cause shown,
- 5 intervene as a party in an action filed by a State under
- 6 paragraph (1).
- 7 "(iii) Notice and an opportunity to be heard with re-
- 8 spect to intervention shall be afforded the State that filed
- 9 the original complaint in any action in which the United
- 10 States files a complaint in intervention under clause (i)
- 11 or a motion to intervene under clause (ii).
- 12 "(iv) The United States may file a petition for appeal
- 13 of a judicial determination in any action filed by a State
- 14 under this section.
- 15 "(C) Service of a State's complaint on the United
- 16 States as required in this paragraph shall be made in ac-
- 17 cord with the requirements of Federal Rule of Civil Proce-
- 18 dure 4(i)(1).
- 19 "(3) For purposes of bringing any civil action under
- 20 paragraph (1), nothing in this Act shall prevent an attor-
- 21 ney general of a State from exercising the powers con-
- 22 ferred on the attorney general of a State by the laws of
- 23 such State to conduct investigations or to administer oaths
- 24 or affirmations or to compel the attendance of witnesses
- 25 of or the production of documentary or other evidence.

1	"(4) Any civil action brought under paragraph (1) in
2	a district court of the United States may be brought in
3	the district in which the defendant is found, is an inhab-
4	itant, or transacts business or wherever venue is proper
5	under section 1391 of title 28, United States Code. Proc-
6	ess in such action may be served in any district in which
7	the defendant is an inhabitant or in which the defendant
8	may be found.
9	"(5) No private right of action is created under this
10	subsection.".
11	(j) Forfeiture of Facilitating Property in
12	DRUG CASES.—Section 511(a)(4) of the Controlled Sub-
13	stances Act (21 U.S.C. 881(a)(4)) is amended to read as
14	follows:
15	"(4) Any property, real or personal, tangible or
16	intangible, used or intended to be used to commit,
17	or to facilitate the commission, of a violation of this
18	title or title III, and any property traceable there-
19	to.''.
20	(k) IMPORT AND EXPORT ACT.—Section 1010(b) of
21	the Controlled Substances Import and Export Act (21
22	U.S.C. 960(b)) is amended—
23	(1) in paragraph (4) by—
24	(A) striking "or any quantity of a con-
25	trolled substance in schedule III, IV, or V, (ex-

1 cept a violation involving flunitrazepam and ex-2 cept a violation involving gamma hydroxy-3 butyrie acid)"; (B) inserting ", or" before "less than one 4 kilogram of hashish oil"; and 5 6 (C) striking "imprisoned" and all that fol-7 lows through the end of the paragraph and in-8 serting "sentenced in accordance with section 9 401(b)(1)(D)of this title $\frac{(21)}{(21)}$ U.S.C. 841(b)(1)(E))."; 10 11 (2) by adding at the end the following: 12 "(5) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule HI, such person shall be sentenced in accordance with sec-15 $\frac{1}{1}$ tion $\frac{401(b)(1)(E)}{1}$. 16 "(6) In the ease of a violation of subsection (a) of this section involving a controlled substance in schedule W (except a violation involving flunitrazepam), such per-19 son shall be sentenced in accordance with section 20 401(b)(2). 21 "(7) In the ease of a violation of subsection (a) of this section involving a controlled substance in schedule V, such person shall be sentenced in accordance with sec-24 tion 401(b)(3)."; and

- 1 (3) in paragraph (3), by striking ", nor shall a
 2 person so sentenced be eligible for parole during the
 3 term of such a sentence" in the final sentence.
- 4 (1) EFFECTIVE DATE.—The amendments made by
 5 this Act shall become effective 60 days after the date of
 6 enactment of this Act.

(m) Guidelines and Regulations.—

- (1) In GENERAL.—The Attorney General may promulgate and enforce any rules, regulations, and procedures which may be necessary and appropriate for the efficient execution of functions under this subtitle, including any interim rules necessary for the immediate implementation of this Act, on its effective date.
- States Sentencing Commission, in determining whether to amend, or establish new, guidelines or policy statements, to conform the guidelines and policy statements to this Act and the amendments made by this Act, may not construe any change in the maximum penalty for a violation involving a controlled substance in a particular schedule as requiring an amendment to, or establishing a new, guideline or policy statement.

1	SECTION 1. SHORT TITLE.
2	This Act may be cited as the "Ryan Haight Online
3	Pharmacy Consumer Protection Act of 2007".
4	SEC. 2. REQUIREMENT OF A VALID PRESCRIPTION FOR
5	CONTROLLED SUBSTANCES DISPENSED BY
6	MEANS OF THE INTERNET.
7	Section 309 of the Controlled Substances Act (21
8	U.S.C. 829) is amended by adding at the end the following
9	new subsection:
10	"(e) Controlled Substances Dispensed by Means
11	OF THE INTERNET.—
12	"(1) No controlled substance may be delivered,
13	distributed, or dispensed by means of the Internet
14	without a valid prescription.
15	"(2) As used in this subsection:
16	"(A) The term 'valid prescription' means a
17	prescription that is issued for a legitimate med-
18	ical purpose in the usual course of professional
19	practice by—
20	"(i) a practitioner who has conducted
21	at least one in-person medical evaluation of
22	the patient; or
23	"(ii) a covering practitioner.
24	``(B)(i) The term 'in-person medical evalua-
25	tion' means a medical evaluation that is con-
26	ducted with the patient in the physical presence

1	of the practitioner, without regard to whether
2	portions of the evaluation are conducted by other
3	health professionals.
4	"(ii) Nothing in clause (i) shall be con-
5	strued to imply that one in-person medical eval-
6	uation demonstrates that a prescription has been
7	issued for a legitimate medical purpose within
8	the usual course of professional practice.
9	"(C) The term 'covering practitioner'
10	means, with respect to a patient, a practitioner
11	who conducts a medical evaluation (other than
12	an in-person medical evaluation) at the request
13	of a practitioner who—
14	"(i) has conducted at least one in-per-
15	son medical evaluation of the patient dur-
16	ing the 24-month period ending on the date
17	of that medical evaluation; and
18	"(ii) is temporarily unavailable to con-
19	duct the evaluation of the patient.
20	"(3) Nothing in this subsection shall apply to—
21	"(A) the delivery, distribution, or dis-
22	pensing of a controlled substance by a practi-
23	tioner engaged in the practice of telemedicine
24	if—

1 "(i) the telemedicine is being conducted 2 while the patient is being treated by, and physically located in, a hospital or clinic 3 4 registered under section 303(f), and the 5 practitioner conducting the practice of tele-6 medicine is registered under section 303(f) 7 in the State in which the patient is located 8 and is acting in the usual course of profes-9 sional practice and in accordance with ap-10 plicable State law; 11 "(ii) the telemedicine is being con-12 ducted while the patient is being treated by, 13 and in the physical presence of, a practi-14 tioner registered under section 303(f) who is 15 acting in the usual course of professional 16 practice, and the practitioner conducting 17 the practice of telemedicine is registered 18 under section 303(f) in the State in which 19 the patient is located and is acting in the 20 usual course of professional practice and in 21 accordance with applicable State law; or 22 "(iii) the telemedicine is being con-23 ducted under any other circumstances that

the Attorney General and the Secretary

have jointly, by regulation, determined to be

24

1	consistent with effective controls against di-
2	version and otherwise consistent with the
3	public health and safety; or
4	"(B) the dispensing or selling of a con-
5	trolled substance pursuant to practices as deter-
6	mined by the Attorney General by regulation,
7	which shall be consistent with effective controls
8	against diversion.".
9	SEC. 3. AMENDMENTS TO THE CONTROLLED SUBSTANCES
10	ACT RELATING TO THE DELIVERY OF CON-
11	TROLLED SUBSTANCES BY MEANS OF THE
12	INTERNET.
13	(a) In General.—Section 102 of the Controlled Sub-
14	stances Act (21 U.S.C. 802) is amended by adding at the
15	end the following:
16	"(50) The term 'Internet' means collectively the
17	myriad of computer and telecommunications facili-
18	ties, including equipment and operating software,
19	which comprise the interconnected worldwide network
20	of networks that employ the Transmission Control
21	Protocol/Internet Protocol, or any predecessor or suc-
22	cessor protocol to such protocol, to communicate infor-
23	mation of all kinds by wire or radio.
24	"(51) The term 'deliver, distribute, or dispense
25	by means of the Internet' refers, respectively, to any

1	delivery, distribution, or dispensing of a controlled
2	substance that is caused or facilitated by means of the
3	Internet.
4	"(52) The term 'online pharmacy'—
5	"(A) means a person, entity, or Internet
6	site, whether in the United States or abroad, that
7	knowingly or intentionally delivers, distributes,
8	or dispenses, or offers or attempts to deliver, dis-
9	tribute, or dispense, a controlled substance by
10	means of the Internet; and
11	"(B) does not include—
12	"(i) manufacturers or distributors reg-
13	istered under subsection (a), (b), (c), or (d)
14	of section 303 who do not dispense con-
15	trolled substances to an unregistered indi-
16	vidual or entity;
17	"(ii) nonpharmacy practitioners who
18	are registered under section 303(f) and
19	whose activities are authorized by that reg-
20	istration;
21	"(iii) mere advertisements that do not
22	attempt to facilitate an actual transaction
23	involving a controlled substance; or
24	"(iv) a person, entity, or Internet site
25	which is not in the United States and does

1 not facilitate the delivery, distribution, or 2 dispensing of a controlled substance by 3 means of the Internet to any person in the 4 United States. 5 "(53) The term 'homepage' means the opening or 6 main page or screen of the website of an online phar-7 macy that is viewable on the Internet. 8 "(54) The term 'practice of telemedicine' means 9 the practice of medicine in accordance with applica-10 ble Federal and State laws by a practitioner (other 11 than a pharmacist) who is at a location remote from 12 the patient and is communicating with the patient, 13 or health care professional who is treating the patient, 14 using a telecommunications system referred to in sec-15 tion 1834(m) of the Social Security Act (42 U.S.C. 16 1395m(m)).". 17 (b) REGISTRATION REQUIREMENTS.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended 18 by adding at the end the following new subsection: 19 20 "(i) Dispenser of Controlled Substances by 21 Means of the Internet.—(1) An online pharmacy shall obtain a registration specifically authorizing such activity, 23 in accordance with regulations promulgated by the Attorney General. In determining whether to grant an applica-

- 1 tion for such registration, the Attorney General shall apply
- 2 the factors set forth in subsection (f).
- 3 "(2) Registration under this subsection shall be in ad-
- 4 dition to, and not in lieu of, registration under subsection
- 5 *(f)*.
- 6 "(3) This subsection does not apply to pharmacies that
- 7 merely advertise by means of the Internet but do not at-
- 8 tempt to facilitate an actual transaction involving a con-
- 9 trolled substance by means of the Internet.".
- 10 (c) REPORTING REQUIREMENTS.—Section 307(d) of
- 11 the Controlled Substances Act (21 U.S.C. 827(d)) is amend-
- 12 *ed by*—
- 13 (1) designating the text as paragraph (1); and
- 14 (2) inserting after paragraph (1), as so des-
- ignated by this Act, the following new paragraph:
- 16 "(2) A pharmacy registered under section 303(i) shall
- 17 report to the Attorney General the controlled substances dis-
- 18 pensed under such registration, in such manner and accom-
- 19 panied by such information as the Attorney General by reg-
- 20 ulation shall require.".
- 21 (d) Online Prescription Requirements.—The
- 22 Controlled Substances Act is amended by inserting after sec-
- 23 tion 310 (21 U.S.C. 830) the following:

1	"ONLINE PHARMACY LICENSING AND DISCLOSURE
2	REQUIREMENTS
3	"Sec. 311. (a) In General.—An online pharmacy
4	shall display in a visible and clear manner on its homepage
5	a statement that it complies with the requirements of this
6	section with respect to the delivery or sale or offer for sale
7	of controlled substances and shall at all times display on
8	$the\ homepage\ of\ its\ Internet\ site\ a\ declaration\ of\ compliance$
9	in accordance with this section.
10	"(b) Licensure.—Each online pharmacy shall com-
11	ply with the requirements of State law concerning the licen-
12	sure of pharmacies in each State from which it, and in
13	each State to which it, delivers, distributes, or dispenses or
14	offers to deliver, distribute, or dispense controlled substances
15	by means of the Internet.
16	"(c) Compliance.—No online pharmacy or practi-
17	tioner shall deliver, distribute, or dispense by means of the
18	$Internet\ a\ controlled\ substance\ without\ a\ valid\ prescription$
19	(as defined in section 309(e)) and each online pharmacy
20	shall comply with all applicable requirements of Federal
21	and State law.
22	"(d) Internet Pharmacy Site Disclosure Infor-
23	MATION.—Each online pharmacy site shall post in a visible
24	and clear manner on the homepage of its Internet site or
25	on a page directly linked from its homepage the following:

1	"(1) The name of the owner, street address of the
2	online pharmacy's principal place of business, tele-
3	phone number, and email address.
4	"(2) A list of the States in which the online
5	pharmacy, and any pharmacy which dispenses, deliv-
6	ers, or distributes a controlled substance on behalf of
7	the online pharmacy, is licensed to dispense controlled
8	substances or prescription drugs and any applicable
9	license number.
10	"(3) For each pharmacy identified on its license
11	in each State in which it is licensed to engage in the
12	practice of pharmacy and for each pharmacy which
13	dispenses or ships controlled substances on behalf of
14	the online pharmacy:
15	"(A) The name of the pharmacy.
16	"(B) The street address of the pharmacy.
17	"(C) The name, professional degree, and li-
18	censure of the pharmacist-in-charge.
19	"(D) The telephone number at which the
20	pharmacist-in-charge can be contacted.
21	"(E) A certification that each pharmacy
22	which dispenses or ships controlled substances on
23	behalf of the online pharmacy is registered under
24	this part to deliver, distribute, or dispense by
25	means of the Internet controlled substances.

- 1 "(4) The name, address, professional degree, and 2 licensure of practitioners who provide medical con-3 sultations through the website for the purpose of pro-4 viding prescriptions.
 - "(5) A telephone number or numbers at which the practitioners described in paragraph (4) may be contacted.
- 8 "(6) The following statement, unless revised by 9 the Attorney General by regulation: 'This online 10 pharmacy will only dispense a controlled substance to 11 a person who has a valid prescription issued for a le-12 gitimate medical purpose based upon a medical rela-13 tionship with a prescribing practitioner, which in-14 cludes at least one prior in-person medical evalua-15 tion. This online pharmacy complies with section 309(e) of the Controlled Substances Act (21 U.S.C. 16 17 829(e)).'.
- "(e) Notification.—(1) Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in the form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

5

6

1	"(2) The notification required under paragraph (1)
2	shall include—
3	"(A) the information required to be posted on the
4	online pharmacy's Internet site under subsection (d.
5	and shall notify the Attorney General and the appli-
6	cable State boards of pharmacy, under penalty of per-
7	jury, that the information disclosed on its Internet
8	site under to subsection (d) is true and accurate;
9	"(B) the online pharmacy's Internet site address
10	and a certification that the online pharmacy shall no-
11	tify the Attorney General of any change in the ad-
12	dress at least 30 days in advance; and
13	"(C) the Drug Enforcement Administration reg-
14	istration numbers of any pharmacies and practi-
15	tioners referred to in subsection (d), as applicable.
16	"(3) An online pharmacy that is already operational
17	as of the effective date of this section, shall notify the Attor-
18	ney General and applicable State boards of pharmacy in
19	accordance with this subsection not later than 30 days after
20	the effective date of this section.
21	"(f) Declaration of Compliance.—On and after the
22	date on which it makes the notification under subsection
23	(e), each online pharmacy shall display on the homepage
24	of its Internet site, in such form as the Attorney General

1	shall by regulation require, a declaration that it has made
2	such notification to the Attorney General.
3	"(g) Reports.—Any statement, declaration, notifica-
4	tion, or disclosure required under this section shall be con-
5	sidered a report required to be kept under this part.".
6	(e) Offenses Involving Controlled Substances
7	IN SCHEDULES III, IV, AND V.—Section 401(b) of the Con-
8	trolled Substances Act (21 U.S.C. 841(b)) is amended—
9	(1) in paragraph (1)—
10	(A) in subparagraph (C), by striking "1
11	gram of" before "flunitrazepam";
12	(B) in subparagraph (D), by striking "or in
13	the case of any controlled substance in schedule
14	III (other than gamma hydroxybutyric acid), or
15	30 milligrams of flunitrazepam"; and
16	(C) by adding at the end the following:
17	" $(E)(i)$ In the case of any controlled substance in
18	schedule III, such person shall be sentenced to a term
19	of imprisonment of not more than 10 years and if
20	death or serious bodily injury results from the use of
21	such substance shall be sentenced to a term of impris-
22	onment of not more than 20 years, a fine not to ex-
23	ceed the greater of that authorized in accordance with
24	the provisions of title 18, or \$500,000 if the defendant

1 is an individual or \$2,500,000 if the defendant is 2 other than an individual, or both.

"(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, or \$1,000,000 if the defendant is an individual or \$5,000,000 if the defendant is other than an individual, or both.

"(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment":

(2) in paragraph (2) by—

23 (A) striking "3 years" and inserting "5 24 years";

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

1	(B) striking "6 years" and inserting "10
2	years"; and
3	(C) striking "after one or more prior con-
4	victions" and all that follows through "have be-
5	come final," and inserting "after a prior convic-
6	tion for a felony drug offense has become final,";
7	and
8	(3) in paragraph (3) by—
9	(A) striking "2 years" and inserting "6
10	years";
11	(B) striking "after one or more convictions"
12	and all that follows through 'have become final,"
13	and inserting "after a prior conviction for a fel-
14	ony drug offense has become final,"; and
15	(C) adding at the end the following "Any
16	sentence imposing a term of imprisonment under
17	this paragraph may, if there was a prior convic-
18	tion, impose a term of supervised release of not
19	more than 1 year, in addition to such term of
20	imprisonment."
21	(f) Offenses Involving Dispensing of Con-
22	TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—
23	Section 401 of the Controlled Substances Act (21 U.S.C.
24	841) is amended by adding at the end the following:

1	"(h) Offenses Involving Dispensing of Con-								
2	TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—(1)								
3	Except as authorized by this title, it shall be unlawful fo								
4	any person to knowingly or intentionally cause or facilitat								
5	the delivery, distribution, or dispensing by means of the								
6	Internet of a controlled substance.								
7	"(2) Examples of activities that violate paragraph (1)								
8	include, but are not limited to, knowingly or inten-								
9	tionally—								
10	"(A) delivering, distributing, or dispensing a								
11	controlled substance by means of the Internet by a								
12	$pharmacy\ not\ registered\ under\ section\ 303 (i);$								
13	"(B) writing a prescription for a controlled sub-								
14	stance for the purpose of delivery, distribution, or dis-								
15	pensation by means of the Internet in violation of								
16	$subsection \ 309(e);$								
17	"(C) serving as an agent, intermediary, or other								
18	entity that causes the Internet to be used to bring to-								
19	gether a buyer and seller to engage in the dispensing								
20	of a controlled substance in a manner not authorize								
21	by sections 303(i) or 309(e); and								
22	"(D) making a material false, fictitious, or								
23	fraudulent statement or representation in the submis-								
24	sion to the Attorney General under section 311.								
25	"(3)(A) This subsection does not apply to—								

1	"(i) the delivery, distribution, or dispensation of
2	controlled substances by nonpractitioners to the extent
3	authorized by their registration under this title;
4	"(ii) the placement on the Internet of material
5	that merely advocates the use of a controlled substance
6	or includes pricing information without attempting
7	to propose or facilitate an actual transaction involv-
8	ing a controlled substance; or
9	"(iii) except as provided in subparagraph (B),
10	any activity that is limited to—
11	"(I) the provision of a telecommunications
12	service, or of an Internet access service or Inter-
13	net information location tool (as those terms are
14	defined in section 231 of the Communications
15	Act of 1934 (47 U.S.C. 231)); or
16	"(II) the transmission, storage, retrieval,
17	hosting, formatting, or translation (or any com-
18	bination thereof) of a communication, without
19	selection or alteration of the content of the com-
20	munication, except that deletion of a particular
21	communication or material made by another
22	person in a manner consistent with section
23	230(c) of the Communications Act of 1934 (47
24	U.S.C. 230(c)) shall not constitute such selection

1 or alteration of the content of the communica-2 tion. 3 "(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting 5 in concert with a person who violates subsection (g)(1). 6 "(4) Any person who knowingly or intentionally violates this subsection shall be sentenced in accordance with 8 subsection (b) of this section.". 9 (q) Publication.—Section 403(c) of the Controlled Substances Act (21 U.S.C. 843(c)) is amended by— 10 11 (1) designating the text as paragraph (1); and 12 (2) adding at the end the following: 13 "(2)(A) Except as authorized by this title, it shall be unlawful for any person by means of the Internet, to know-14 15 ingly advertise the sale or distribution of, or to offer to sell, distribute, or dispense, a controlled substance. 17 "(B) Examples of activities that violate subparagraph 18 (A) include, but are not limited to, knowingly or intentionally causing the placement on the Internet of an advertisement that refers to or directs prospective buyers to Inter-21 net sellers of controlled substances who are not registered 22 under section 303(i). 23 "(C) Subparagraph (A) does not apply to material that either—

1	"(i) merely advertises the distribution of con-
2	trolled substances by nonpractitioners to the extent
3	authorized by their registration under this title; or
4	"(ii) merely advocates the use of a controlled
5	substance or includes pricing information without at-
6	tempting to facilitate an actual transaction involving
7	a controlled substance.".
8	(h) Injunctive Relief.—Section 512 of the Con-
9	trolled Substances Act (21 U.S.C. 882) is amended by add-
10	ing to the end of the section the following new subsection:
11	"(c) State Cause of Action Pertaining to Online
12	Pharmacies.—(1) In any case in which the State has rea-
13	son to believe that an interest of the residents of that State
14	has been or is being threatened or adversely affected by the
15	action of a person, entity, or Internet site that violates the
16	provisions of section 303(i), 309(e), or 311, the State may
17	bring a civil action on behalf of such residents in a district
18	court of the United States with appropriate jurisdiction—
19	"(A) to enjoin the conduct which violates this
20	section;
21	"(B) to enforce compliance with this section;
22	"(C) to obtain damages, restitution, or other
23	compensation, including civil penalties under section
24	402(b): and

- 1 "(D) to obtain such other legal or equitable relief
- 2 as the court may find appropriate.
- 3 "(2)(A) Prior to filing a complaint under paragraph
- 4 (1), the State shall serve a copy of the complaint upon the
- 5 Attorney General and upon the United States Attorney for
- 6 the judicial district in which the complaint is to be filed.
- 7 In any case where such prior service is not feasible, the
- 8 State shall serve the complaint on the Attorney General and
- 9 the appropriate United States Attorney on the same day
- 10 that the State's complaint is filed in Federal district court
- 11 of the United States. Such proceedings shall be independent
- 12 of, and not in lieu of, criminal prosecutions or any other
- 13 proceedings under this title or any other laws of the United
- 14 States.
- 15 "(B)(i) Not later than 120 days after the later of the
- 16 date on which a State's complaint is served on the Attorney
- 17 General and the appropriate United States Attorney, or the
- 18 date on which the complaint is filed, the United States shall
- 19 have the right to intervene as a party in any action filed
- 20 by a State under paragraph (1).
- 21 "(ii) After the 120-day period described in clause (i)
- 22 has elapsed, the United States may, for good cause shown,
- 23 intervene as a party in an action filed by a State under
- 24 paragraph (1).

- 1 "(iii) Notice and an opportunity to be heard with re-
- 2 spect to intervention shall be afforded the State that filed
- 3 the original complaint in any action in which the United
- 4 States files a complaint in intervention under clause (i)
- 5 or a motion to intervene under clause (ii).
- 6 "(iv) The United States may file a petition for appeal
- 7 of a judicial determination in any action filed by a State
- 8 under this section.
- 9 "(C) Service of a State's complaint on the United
- 10 States as required in this paragraph shall be made in ac-
- 11 cord with the requirements of Federal Rule of Civil Proce-
- 12 dure 4(i)(1).
- 13 "(3) For purposes of bringing any civil action under
- 14 paragraph (1), nothing in this Act shall prevent an attor-
- 15 ney general of a State from exercising the powers conferred
- 16 on the attorney general of a State by the laws of such State
- 17 to conduct investigations or to administer oaths or affirma-
- 18 tions or to compel the attendance of witnesses of or the pro-
- 19 duction of documentary or other evidence.
- 20 "(4) Any civil action brought under paragraph (1) in
- 21 a district court of the United States may be brought in the
- 22 district in which the defendant is found, is an inhabitant,
- 23 or transacts business or wherever venue is proper under sec-
- 24 tion 1391 of title 28, United States Code. Process in such

1	action may be served in any district in which the defendant						
2	is an inhabitant or in which the defendant may be found.						
3	"(5) No private right of action is created under this						
4	subsection.".						
5	(i) Forfeiture of Facilitating Property in						
6	Drug Cases.—Section 511(a)(4) of the Controlled Sub-						
7	stances Act (21 U.S.C. 881(a)(4)) is amended to read as						
8	follows:						
9	"(4) Any property, real or personal, tangible or						
10	intangible, used or intended to be used to commit, or						
11	to facilitate the commission, of a violation of this title						
12	or title III, and any property traceable thereto.".						
13	(j) Import and Export Act.—Section 1010(b) of the						
14	Controlled Substances Import and Export Act (21 U.S.C.						
15	960(b)) is amended—						
16	(1) in paragraph (4) by—						
17	(A) striking "or any quantity of a con-						
18	trolled substance in schedule III, IV, or V, (ex-						
19	cept a violation involving flunitrazepam and ex-						
20	cept a violation involving gamma hydroxy-						
21	butyric acid)";						
22	(B) inserting ", or" before "less than one						
23	kilogram of hashish oil"; and						
24	(C) striking "imprisoned" and all that fol-						
25	lows through the end of the paragraph and in-						

1 serting "sentenced in accordance with section 2 of401(b)(1)(D)this title(21 U.S.C.841(b)(1)(E))."; 3 (2) by adding at the end the following: 4 5 "(5) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule III, such person shall be sentenced in accordance with section 8 401(b)(1)(E). 9 "(6) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule IV (ex-10 cept a violation involving flunitrazepam), such person shall be sentenced in accordance with section 401(b)(2). 13 "(7) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule V, such 14 15 person shall be sentenced in accordance with section 401(b)(3)."; and 16 17 (3) in paragraph (3), by striking ", nor shall a 18 person so sentenced be eligible for parole during the 19 term of such a sentence" in the final sentence. 20 (k) Effective Date.—The amendments made by this Act shall become effective 60 days after the date of enact-22 ment of this Act. 23 (1) Guidelines and Regulations.— 24 (1) In General.—The Attorney General may 25 promulgate and enforce any rules, regulations, and

- procedures which may be necessary and appropriate
 for the efficient execution of functions under this subtitle, including any interim rules necessary for the
 immediate implementation of this Act, on its effective
 date.
 - (2) Sentencing Guidelines.—The United States Sentencing Commission, in determining whether to amend, or establish new, guidelines or policy statements, to conform the Federal sentencing guidelines and policy statements to this Act and the amendments made by this Act—
 - (A) shall consult with the Department of Justice, experts and other affected parties concerning which penalties for scheduled substances amended by this Act should be reflected in the Federal sentencing guidelines; and
 - (B) should not construe any change in the maximum penalty for a violation involving a controlled substance in a particular schedule as being the sole reason to amend a, or establish a new, guideline or policy statement.
- 22 (m) ANNUAL REPORT.—Not later than 180 days after 23 the date of enactment of this Act, and annually for 2 years 24 after the initial report, the Drug Enforcement Administra-

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

1	tion,	in	consultation	with	the	Department	of	State,	shall
2	subm	it t	o Congress a i	report	dese	cribing—			

- (1) the foreign supply chains and sources of controlled substances offered for sale without a valid prescription on the Internet;
 - (2) the efforts and strategy of the Drug Enforcement Administration to decrease the foreign supply chain and sources of controlled substances offered for sale without a valid prescription on the Internet; and
- (3) the efforts of the Drug Enforcement Administration to work with domestic and multinational pharmaceutical companies and others to build international cooperation and a commitment to fight on a global scale the problem of distribution of controlled substances over the Internet without a valid prescription.

Calendar No. 617

110th Congress S. 980

A BILL

To amend the Controlled Substances Act to address online pharmacies.

March 12, 2008

Reported with an amendment